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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)
133171.02001

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on _____

Signature _____

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Application Number	Filed
10560650	May 9, 2006

First Named Inventor
David B Weiner

Art Unit	Examiner
1632	Wu Cheng Winston Shen

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- ☐ applicant/inventor.
- ☐ assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- ☑ attorney or agent of record. Registration number 33229.
- ☐ attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____

/Mark DeLuca, Reg. No. 33,229/
Signature

Mark DeLuca
Typed or printed name

610.640.7855
Telephone number

June 22, 2010
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Weiner, *et. al.*		**Confirmation No.**	2255
Serial No.:	10/560,650	**Group Art Unit:**	1632
Filed:	May 9, 2006	**Examiner:**	Wu Cheng Winston Shen

Title: **NUCLEIC ACID SEQUENCES ENCODING AND COMPOSITIONS COMPRISING IGE SIGNAL PEPTIDE AND/OR IL-15 AND METHODS FOR USING THE SAME**

Mail Stop:
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Dear Sir:

This Pre-Appeal Brief Request for Review is being filed with a Notice of Appeal in connection with the above-identified patent application. An amendment after final was filed on March 22, 2010. The Advisory action dated April 7, 2010 indicates that the amendment would be entered. Accordingly, claims 1, 14-17, 19, 38, 55-60, 64, 66-71, 75 and 77 are pending of which claims 1, 14-17, 19, 55-60, 66-71 and 77 stand rejected and claims 38, 64 and 75 are withdrawn from consideration. The five rejections and the issue of the premature finality of the rejection are discussed below. The arguments are consistent with those included in the response after final. The remarks below supplement those earlier remarks and address the issues as clarified in the Advisory Action.

1) The finality of the rejection was premature.

Claims 1 and 77 were newly rejected under 35 U.S.C. 103(a) in the Official Action dated January 22, 2010. The Office incorrectly stated that the rejection was necessitated by Applicants' amendment. The rejection as applied to claim 1 could have been applied to claim 1 prior to the amendment, i.e.the amendment did not necessitate the new grounds for rejection. The Office stated claim 1 was rejected because including the independent claim is standard form in a 103 rejection. Regardless, if independent claim 1 is deemed obvious for the first time and the rejection is not necessitated by an amendment to claim 1, it is improper to deem the rejection final. The finality of the rejection should have been withdrawn. If the 103 rejection is not reversed, prosecution should be reopened.

2. Claim 66 is incorrectly rejected as indefinite

Claim 66 is asserted to indefinite because it included the phrase "the non-IgE protein" which is set forth in two different subparagraphs containing two alternative limitations in claim 1 from which claim 66 depends. The Office deems claim 66 unclear and suggests the claim does not distinguish and identify to which of the two subparagraphs the phrase "the non-IgE protein" in claim 66 refers. The two alternative limitations are not mutually exclusive. One limitation refers to "a non-IgE protein from the same species as the IgE signal peptide"; the other refers to a non-IgE protein that is one of several expressly recited immunomodulatory proteins. That is, the first alternative limitation allows that if the non-IgE, protein is from the same species as the IgE signal peptide, the non-IgE peptide can be any protein. The second alternative limitation allows that the non-IgE protein can only be one of several expressly recited immunomodulatory proteins but is silent with respect to whether or not it is from the same species or not as the IgE signal peptide. One skilled in the art could readily determine the metes and bounds of the claim and ascertain whether or not something infringes or is outside the scope of the claim. The rejection of claim 66 as indefinite is incorrect and should be reversed.

3) **Claims 1, 14-17, 19, 55-60 and 66-71 have been rejected anticipated by Weiner.**
4) **Claims 1, 14, 16, 17, 19, 55, 56, 58-60, 66, 67 and 69-71 have been rejected anticipated by Yang (J Inf Dis 2001).**
5) **Claims 1, 14, 16, 17, 19, 55, 56, 58-60, 66, 67 and 69-71 have been rejected anticipated by Yang (Emer Inf Dis 2002).**

Each of these three anticipation are incorrect because in each instance the Office has incorrectly interpreted the clear and well established meaning of claim terms and used in there place. Claim 1 refers to "a nucleic acid sequence" which is either

> a nucleic acid sequence that encodes a fusion protein that consists of a non-IgE protein sequences linked to an IgE signal peptide that is from the same species as the non-IgE protein

or

> a nucleic acid sequence that encodes a fusion protein that consists of a non-IgE protein sequences linked to an IgE signal peptide, wherein the non-IgE protein is an immunomodulating protein selected from the group consisting of cytokines, chemokines, cellular death receptors, cellular adhesion molecules, cellular growth factors, cellular growth factor receptors, protein kinases and enzymes or functional fragment thereof.

Neither Weiner nor Yang 2001 nor Yang 2002 anticipate the claim. Rather, each reference discloses constructs having coding sequences for a fusion protein comprising a human Ig signal

peptide linked to a West Nile Virus (WNV) capsid protein. The phrase "from the same species as the non IgE protein" has been interpreted to encompass "obtained from the same species". Since viral proteins such as WNV capsid protein must be obtained from a host species because viruses can't make proteins on their own, the Office asserts that WNV capsid protein is a human protein, presumably since WNV capsid protein can be made in humans infected with WNV. Thusthe Office concludes constructs in each reference having nucleic acids molecules encoding fusion proteins comprising a human Ig signal peptide linked to a WNV capsid protein are nucleic acids encoding fusion proteins comprising a human signal peptide linked to a human protein.

The interpretation of the claim and how it is used to characterize the teachings in the cited references is unreasonable and cannot be properly used to reject the claims as anticipated. The Office's suggestion that viral proteins from viruses which can infect humans are human proteins is unreasonable. Nothing in the application suggests Applicants intended this unusual construction which is contrary to ordinary usage. Rather, the application uses the terms with their ordinary, well established and recognized meanings. One skilled in the art would not refer to viral protein as a human protein and an interpretation of the claim that supports such a conclusion is an unreasonable interpretation. Claims must be given their broadest **reasonable** interpretation.

The assertion by the Office that the phrase "from the same species as the non IgE protein" encompasses "obtained from the same species" expands the phrase beyond the ordinary manner in which the claim language is applied. Using the interpretation offered by the Office results in constructions which are contrary to the ordinary meaning of the terms and is therefore not unreasonable. For these reasons, the anticipation rejections are incorrect and should be reversed.

6) **Claims 1 and 77 have been rejected as obvious over Yang (J Inf Dis 2001) in view of Letvin, (WO 99/16466).**

Yang 2001 is discussed above. Letvin is cited for disclosing the use of plasmids that encode expressible IL-15 to enhance immune responses. The combination of Yang 2001 and Letvin do not render claims 1 and 77 obvious. The Office asserts that one skilled in the art would replace the WNV capsid protein with the IL-15 sequence of Letvin. The Official Action indicates that Yang 2001 teaches that antigen specific immune responses were observed when constructs encoding WNV capsid limked to IgE signal were injected into mice and that Letvin teaches induction of immune responses using construct encoding various immunomodulatory proteins. The Office asserts that it would be obvious to exchange the WNV capsid encoding

sequences with IL-15 encoding sequences taught by Letvin. This is incorrect. First, doing so destroys the purpose of Yang 2001 which is to induce anti-WNV capsid specific immune responses. Second, Letvin teaches using an IL-15 signal peptide and that immunomodulatory proteins to boost immunity. Combining it with Yang as asserted by the Office requires using a protein that boosts immunity in place of the protein against which immunity is sought. In the Advisory Action, the Office asserts the choice of signal peptide would be one of routine optimization and refers to the section of the MPEP entitled "Optimizatoin of Ranges". Applicants note that the optimization referred to by the Office pertains to optimizing conditions such amounts, temperature, pressure etc used in processes. That law does not properly support the rejection of claims 1 and 77 as obvious.

Yang 2001 and Letvin would not be combined by one skilled in the as suggested by the Office. The combination destroys the purpose of Yang 2001. The two inserts – WNV capsid protein and IL-15 – are not interchangeable and do not have a common function. It would also not be obvious to one skilled in the art to substitute the coding sequence for an IgE signal peptide in place of the IL-15 signal peptide coding sequences of an IL-15 coding sequence. The resulting construct provides unexpected results, further demonstrating its non-obviousness. The incorrect rejection of claims 1 and 77 should be reversed.

Respectfully submitted,

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Dated: June 22, 2010

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